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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,634	12/14/2001	Ronenn Roubenoff	21629-004	1772

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,634	ROUBENOFF ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-13 are currently pending for prosecution on the merits. No amendment has been presented in the Applicant's response filed March 09, 2006.

Response to Argument

2. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-4 which depend on the independent claim 2 recite "said reduced folate compound is present in an amount from 0.01mg to 500mg and said cobalamin compound is present in and amount from 0.0002 mg to 10mg" and "said reduced folate compound is present in an amount from 0.1mg to 50mg and said cobalamin compound is present in and amount from 0.002 mg to 1mg" respectively. Accordingly to the claim 2, the weight ratio of the reduced folate compound to cobalamin must be in 125:1 (at all times). In other words, the range of amounts of the reduced folate compound and the range of amounts of cobalamin must be present in said composition in the exact proportion to make final composition in 125:1 ratio. For

instance, when the upper limit of the cobalamin is used, for example 10mg or 1mg in claims 3-4, the amount of the reduced folate must be either 1250mg or 125mg. However, the upper limits of the reduced folate in claims 3 and 4 are 500mg and 50 respectively. This inconsistency leaves the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear. In this regard, although the specific embodiments are shown in the specification (Examples), it is considered that the meaning of the claims should be clear from the wording of the claim alone.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-5, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (US 6011040).

Muller teaches a composition comprising reduced folate compound (i.e., 5-formyl-(6S)-tetrahydrofolic acid, 5-methyl-(6S)-tetrahydrofolic acid, 5,10,methylene-(6R)-tetrahydrofolic acid, 5,10,methenyl-(6R)-tetrahydrofolic acid, 10-formyl-(6R)-tetrahydrofolic acid, 5-formimino-(6S)-tetrahydrofolic acid or (6S)-tetrahydrofolic acid) together with vitamin B (i.e., vitamin B12), wherein an amount of said reduced folate compound is in dose range between 0.001mg and 1000mg, and an amount of said vitamin B12 is in dose range of 0.001mg and 0.5mg (column 2, lines 19-25; column 3, lines 9-21 and lines 30-40; Example 10; claims 5, 19-20).

The teaching of Muller differs from the claimed invention in the specific ratio of the folate compound and the cobalamin is 125:1.

However, those of ordinary skilled in the art would have been readily optimized effective dosage ratio in light of Muller who teaches the range of amounts of the reduced folate compound and cobalamin (vitamin B12) in said composition. One having ordinary skilled in the art would have expected as taught by Muller that said composition could be formulated in the ratio of the reduced folate to cobalamin between 1:1 (when the lower limit of the reduced folate (e.g., 0.001mg) is compared to the lower limit of the cobalamin (e.g., 0.001mg)) to 1:2000 (when

the upper limit of the reduced folate (e.g., 1000mg) is compared to the upper limit of the cobalamin (e.g., 0.5mg)). Based on Muller, one having ordinary skilled in the art would have been able to arrive at the claimed ratio without undue amount of experimentation. Thus, Muller makes obvious the instant invention.

With respect to "chondroprotective effect" of the said composition, such property or feature is not limiting to the interpretation of the composition claim. Even if the examiner gives a patentable weight to such property, such property is considered to be the expected feature of the claimed composition when the ratio of said reduced folate and said cobalain is in 125:1. Therefore, Muller makes obvious the instant invention.

5. Claims 6-8 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (US 6011040) in view of Smith et al. (WO 98/19690).

The teaching of Muller has been discussed above 35 USC 103(a) rejection. The modified teaching of Muller includes all that is recited in claims 6-8 and 11-13 except the incorporation of betaine, particularly in dosage range of "from 500 mg to 20,000mg" or "from 500mg to 2000mg", in said composition.

Smith teaches a composition comprising (i) folic acid, betaine and vitamin B12 or (ii) folate or folate derivatives (e.g., tetrahydrofolic acid, 5,10-methylenetetrahydrofolate, 5-methyltetrahydrofolate, 5,10-methyenyltetrahydrofolate, 5-fomyltetrahydrofolate, etc...), betaine and vitamin B12, wherein said composition can be prepared in single fixed combination such as single tablet or single capsule (page 4, line 34 thru page 5, line 20; page 10, lines 3-6; page 11, lines 3-9; Example 1; claims 25 and 27). Smith also expressly teaches that (i) the folic acid or folate or derivatives is employed in a weight ratio to vitamin B12 of within the range from about

0.1:1 to about 50:1 and preferably from about 0.2:1 to about 25:1 (column 6, lines 5-8); and (ii) the folic acid or folate or derivative or betaine is employed in daily oral doses within the range from about 0.1 to about 100mg, and vitamin B12 is employed in daily oral doses within the range from about 0.001 mg to abut 10mg (column 6, lines 41-47).

One having ordinary skilled in the art would have expected as taught by Smith that the use of secondary ingredient such as betaine in composition containing folic acid, folate or folate derivatives and vitamin B12 is old and well known. Furthermore, above references in combination make clear that the determination of the claimed dosage amounts of betaine is well within the skill of the artisan since the dosage amounts of betaine disclosed in Smith overlaps with the claimed dosage amount of betaine.

Although the instant claims use the different name for the said ingredient than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614